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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,558	01/22/2001	Timothy B. Meluch	ALT-5612 CON of DIV I	3046
29200	7590 01/28/2003			
BAXTER HEALTHCARE CORPORATION			EXAMINER	
RENAL DIVISION 1 BAXTER PARKWAY			FORTUNA, ANA M	
DF3-3E DEERFIELD	, IL 60015		ART UNIT	PAPER NUMBER
	•		1723	/3
			DATE MAILED: 01/28/2003	10

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.

09/767,558

Applicant(s)

Meluch et al

Office Action Summary

Examiner Ana Fortuna Art Unit **1723** 

The MAILING DATE of this communication appears on the cover sheet with the correspondence address				
Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.				
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In mailing date of this communication.</li> </ul>	no event, however, may a reply be timely filed after SIX (6) MONTHS from the			
<ul> <li>If the period for reply specified above is less than thirty (30) days, a reply within the NO period for reply is specified above, the maximum statutory period will apply Failure to reply within the set or extended period for reply will, by statute, cause to Any reply received by the Office later than three months after the mailing date of earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>	and will expire SIX (6) MONTHS from the mailing date of this communication. he application to become ABANDONED (35 U.S.C. § 133).			
Status				
1) $\overline{\mathbb{X}}$ Responsive to communication(s) filed on $\underline{Nov 12}$ ,	2002			
2a)   ☐ This action is FINAL.  2b) ☐ This action is FINAL.	tion is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.				
Disposition of Claims				
4) 💢 Claim(s) <u>1-18</u>	is/are pending in the application.			
4a) Of the above, claim(s)	is/are withdrawn from consideration.			
5) Claim(s)	is/are allowed.			
6) X. Claim(s) <u>1-18</u>	is/are rejected.			
7) Claim(s)	is/are objected to.			
8) Claims	are subject to restriction and/or election requirement.			
Application Papers				
9) $\square$ The specification is objected to by the Examiner.				
10) The drawing(s) filed on is/are	e a) $\square$ accepted or b) $\square$ objected to by the Examiner.			
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) The proposed drawing correction filed on	is: a) approved b) disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. §§ 119 and 120				
13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) All b) Some* c) None of:	·			
1. Certified copies of the priority documents have been received.				
2.   Certified copies of the priority documents have	ve been received in Application No			
application from the International Bure				
*See the attached detailed Office action for a list of the				
14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).				
a) The translation of the foreign language provisional application has been received.  15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.				
•	priority under 35 0.3.C. 33 120 and/or 121.			
Attachment(s)  1) Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).			
Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal Patent Application (PTO-152)			
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)				

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### Claim Rejections - 35 U.S.C. § 112

1. Claims 5-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is unclear as to whether a membrane made from the claimed composition is intended, or as to whether the non-solvent is present in the final membrane. For examination purpose all the claims will be considered as homogeneous polysulfone semipermeable membranes. In membranes made from solvent and non-solvents, the non solvent (or pore forming agent) is not part of the final "membrane" product.

# Claim Rejections - 35 U.S.C. § 102

2. Claims 1,3, 5, 6, 8, 10, 12, 16, 17, 18, are rejected under 35 U.S.C. 102(b) as being anticipated by Azad et al (5,462,867)(hereinafter '867). Reference '867 discloses a polysulfone membrane which is substantially isotropic, e.g. having uniform pore structure though a thickness of the polysulfone membrane (abstract, column 9, lines 40-47). The membrane is made from polyethersulfone, as claimed in claims 3, and 16 (column 10, lines 49-56, column 11, lines 11-14). The membrane composition including the solvent and non-solvent is also disclosed (column 14, lines 51-58). The list of solvent and non-solvents is also disclosed in reference '867, column 15, lines 62-68, and column 16, lines 1-65 through column 17, lines 1-17). The membrane composition of claim 10 is also disclosed, e.g. 20 % of PES (column 16, lines 25-28).

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- 3. Claims 1, 2, 3, 6, 7, 5, 6, 8, 9, 10, 11, 12, 15, 16, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Nguyen (5,096,585)(hereinafter '585). Reference '585 discloses "homogeneous" polysulfone microporous membrane of claims 1, 5, and 16, the membranes are made from mixtures of solvent and nonsolvent, the specific solvents and non solvents and polysulfone, polyether sulfone materials of the dependent claims are also disclosed column 2, lines 6-29, column 3, lines 6-18, and lines 65-68). The solvents, polymers ad non solvents of claims 16, 2, 3, 12, 17 and 18 are discloses in '585 (column 5, lines 2-57, column 6, lines 34-68, through column 7, lines 1-39, column 8, lines 16-32). The membrane composition of claims 10, 11, and 15 is also disclosed, e.g. 8-35 % of polysulfone polymer, the solvent and additive composition is also disclosed which averages the limitation of claim 15 (column 6, lines 61-68, column 7, lines 1-4, column 8, lines 60-68, and column 9, lines 1-5). As to claims 8-9, polyether sulfone and bisphenol A polysulfone are disclosed in reference to polysulfone of Udel TM 3500 and 1700 from Amoco.
- 4. Claims 1, 5, 6, 7, 8, 16, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraus et al (4,900,449) ('449). Reference '449 discloses a microporous inherently homogeneous membrane made from polysulfone polymer in a mixture of solvent and non solvent, polysulfone and polyether sulfone are disclosed as suitable polymers (column 3, lines 11-68, column 4, lines 1-29, column 5, lines 35-68, through column 6, lines 1-66, column 7, lines 21-68, and column 8, lines 1-20). '449 also disclosed DMF and PEG, etc (column 9, lines 30-68 through column 10, lines 1-30).

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## Claim Rejections - 35 U.S.C. § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 2, 4, 7, 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azad et al (5,462,867)('867) in view of Pemawansa (5,279,739)(hereinafter '739). Reference '867 fails to disclose polyarylsulfone, and the solvent of the solvents of claims 4 and 13-14. Reference '739 teaches the claimed solvents as solvent for polysulfone, e.g. sulfolane (column 5, lines 59-65). It would have been obvious to one skilled in the art at the time the invention was made to substitute conventional polysulfone solvents, such as DMF, DMA, disclosed in reference '867, by sulfolane (tetraethylene sulfone) as suggested by '739 in a process of making a membrane from polysulfone. Reference '739 also discloses polyether sulfone and polyarylether sulfone as equivalents in the art for producing membranes (column 10, lines 25-29). It wold have been obvious to one skilled in the art at the time the invention was made to produce a membrane from polysulfone, e.g. polyarylsulfone or polyether sulfone and having the properties and composition of the membrane of '867, since these polysulfones are art recognized equivalents.
- 7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reference 5,906,742 is cited as art recognizing the membrane of Kraus as isotropic (homogeneous) membrane (column 9, lines 14-16). References 6,026968, and 4,780,205 are

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cited as listening conventional polysulfone solvents and nonsolvents. Additional prior art is also considered to be pertinent to Applicant's disclosure.

#### Response to Arguments

8. Applicant's arguments filed on 11/12/02 have been fully considered but they are not persuasive. The 112 rejection is maintained, Applicant's argues that the claims are directed to a membrane including polysulfone, solvent and non-solvent, however, the specification is silent regarding to the presence of the non-solvent in the final product or membrane. The specification does discloses the composition use in making the membrane, which includes polysulfone, solvent and non-solvent, the membrane can be made by conventional process, which includes quenching and or drying the membrane, which can extract the non-solvent or pore former from the composition before the membrane is completely formed, therefore the non-solvent can be use only for forming pores and further extracting it before recovering the final membrane product. For this reason the rejection is maintained. As to applicant's arguments regarding to the membrane "uniform structure throughout the thickness", applicant's define the term (see paper No. 11, section "Remarks", page 3, paragraph 1), as "symmetric (isotropic). Reference to Azad et al (\*867) teaches "isotropic" (abstract), and further suggests its methods for producing isotropic membranes in all directions throughout the membrane (column 9, lines 44), in column 7, lines 6-8, Azad et al also teaches how to make isotropic membranes from solvent and non solvent and polysulfone mixtures and void skin formation and anisotropy. The rejection is also maintained.

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As to reference to Nguyen ('585), this reference discloses the membrane as "nearly homogeneous from surface to surface (column 2, lines 6-11, the membrane composition is also disclosed, leaching out the non-solvent from the membrane composition during membrane precipitation, the membrane composition is also disclosed as discussed above (column 3, lines 6-40). Reference '585 also discloses producing a polysulfone membrane, "homogenous" and containing the non-solvent, or a portion of the non-solvent (poe former) which is not leached out during the process of making the membrane, e.g. high molecular weight PEG (as pore former or non-solvent) (column 7, lines 26-38). This rejection is also maintained. Regarding rejection based on Kraus et al, as discussed above, this membrane is well recognized as isotropic or symmetrical membrane and is made form the claimed composition. Eguchi and Muller further teach conventional polysulfone solvents and non-solvents.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CAR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310 for regular responses, and (703) 872-9311 for after finals.

Ana Fortuna

January 22, 2003

ANA FORTUNA
PRIMARY EXAMINER